



Rapid Litigation
Management Ltd. v.
CellzDirect, Inc., No. 2015-
1570 (Fed. Cir. July 5, 2016)

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Spoilers

- Rapid Litigation Management appealed the summary judgment determination of the District Court for the Northern District of Illinois that U.S. Patent No. 7,604,929 is invalid under 35 U.S.C. § 101.



Spoilers

- The district court concluded that the '929 Patent is directed to a patent-ineligible law of nature (i.e., that hepatocytes are capable of surviving multiple freeze-thaw cycles) and that the patented process lacks the requisite inventive concept.

Spoilers

- The Federal Circuit held that the claims of the '929 Patent are not directed to a patent-ineligible concept, so the district court's decision was vacated and remanded.

Background

- Hepatocytes are a type of liver cell that are useful for testing, diagnostic, and treatment purposes.
- Fresh hepatocytes have a short lifespan.
- Prior to the '929 Patent, scientists used cryopreservation techniques comprising freezing the hepatocytes, thawing them when needed, and recovering the viable cells.

Background

- However, this process damaged the hepatocytes, leading to poor recovery numbers of viable cells.
- As such, it was considered that hepatocytes could only be frozen once and then used or discarded.

Background

- The inventors discovered that cells twice frozen behaved like cells that were once frozen.
- In other words, if the cells survived the first freeze, at least 70% of the cells would survive subsequent



Facts

- Claim 1 of U.S. Patent No. 7,604,929 recites:
- A method of producing a desired preparation of multi-cryopreserved hepatocytes, said hepatocytes, being capable of being frozen and thawed at least two times, and in which greater than 70% of the hepatocytes of said preparation are viable after the final thaw, said method comprising:
 - (A) subjecting hepatocytes that have been frozen and thawed to density gradient fractionation to separate viable hepatocytes from non-viable hepatocytes,
 - (B) recovering the separated viable hepatocytes, and
 - (C) cryopreserving the recovered viable hepatocytes to thereby form said desired preparation of hepatocytes without requiring a density gradient step after thawing the hepatocytes for the second time, wherein the hepatocytes are not plated between the first and second cryopreservations, and wherein greater than 70% of the hepatocytes of said preparation are viable after the final thaw.

Commercial Embodiment

LiverPool™ Cryoplateable Human Hepatocytes

- Select a product -



Hepatocytes from BioreclamationIVT are cryopreserved the same day they are isolated, and come with full serology reporting for your safety. LiverPool cryoplateable human hepatocytes are used for long term studies (≥ 4 hours) like induction, toxicity, and transport. More recently, scientists also have been using cryoplateable hepatocytes to study transporter uptake, viral transduction and gene induction.

BioreclamationIVT's LiverPool cryoplateable human hepatocytes have high levels of induction following treatment with known inducers omeprazole (CYP1A2), phenobarbital (CYP2B6), and rifampin (CYP3A4). All plateable lots have greater than 70% viability and greater than 70% confluence on day 5. Cells are also treated with CDFDA fluorescent dye to show bile caniculi formation.

The process for producing the LiverPool™ pooled human hepatocyte products is covered by one or more U.S. or foreign patents and patent applications, including U.S. Patent No. 7,604,929.

Facts

- Rapid Litigation Management sued CellzDirect for infringing the '929 Patent.
- In response, CellzDirect filed a motion for summary judgment of invalidity under 35 U.S.C. § § 101 and 112.
- The district court granted the motion with respect to § 101 without reaching the § 112 issues.

District Court

- The district court (N.D. Ill.) applied the Supreme Court's two-step framework for determining patent eligibility.

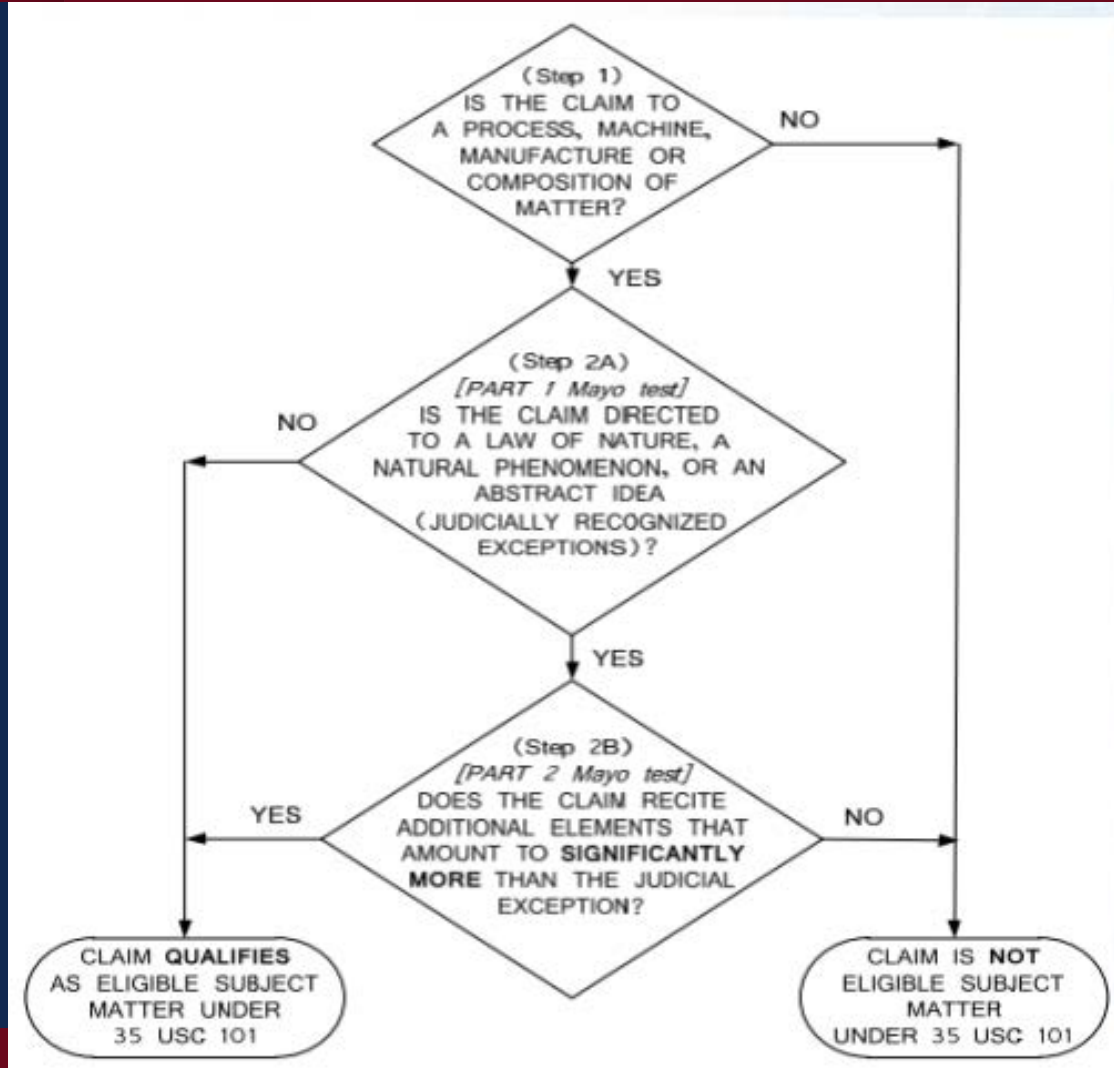
District Court

- Step one of the two-part test articulated by the Supreme Court for issues under 35 U.S.C. § 101 asks whether the claim is directed to one of the patent-ineligible concepts.
- If the answer is no, the claim recites patent-eligible subject matter.
- If the answer is yes, the test proceeds to step two.

District Court

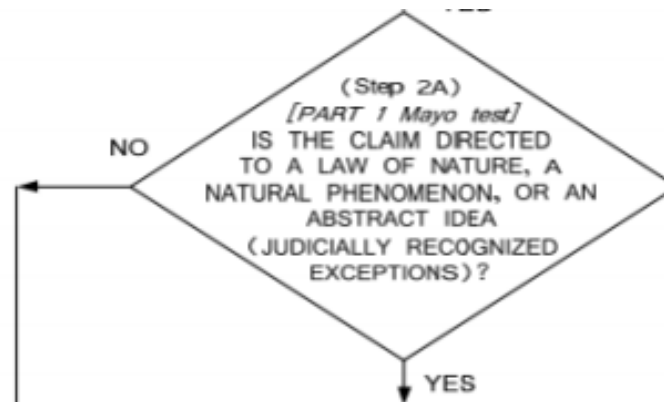
- Step two asks whether the additional elements transform the nature of the claim into a patent-eligible application.

2014 Interim Eligibility Guidance



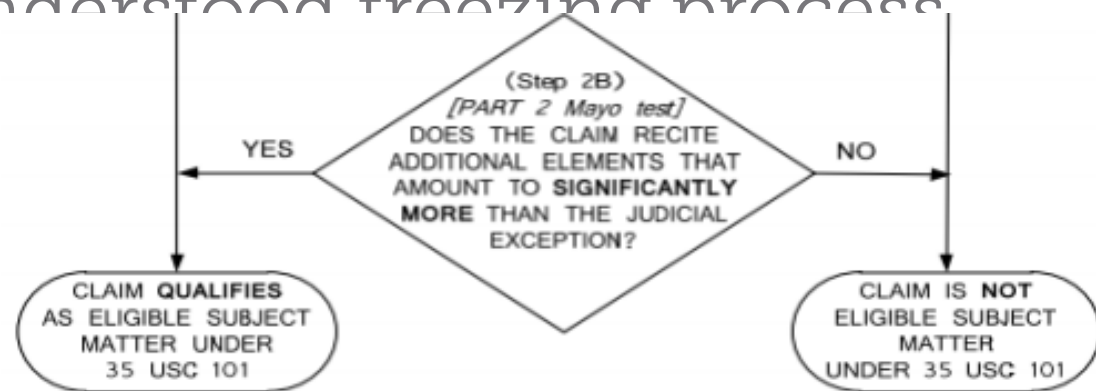
District Court

- At step one, the district court concluded that the '929 Patent is directed to an ineligible law of nature.



District Court

- At step two, the district court determined that the patented process lacks the requisite inventive concept since the inventors reapplied a well-understood freezing process.



District Court

- Rapid Litigation Management appealed the district court's decision.

Federal Circuit – Step One

- For step one, the district court concluded that the patent is directed to an ineligible law of nature with respect to the discovery that hepatocytes are capable of surviving multiple freeze-thaw cycles.
- The Federal Circuit disagreed with this conclusion.

Federal Circuit – Step One

- The Federal Circuit noted that the claims are not simply directed to the ability of hepatocytes to survive multiple freeze-thaw cycles.
- Rather, the claims are directed to a new and useful laboratory technique for preserving hepatocytes.

Federal Circuit – Step One

- Although the inventors discovered the cells' ability to survive multiple freeze-thaw cycles, the inventors then applied their natural discovery to create a new and improved way of preserving hepatocyte cells for later use.

Federal Circuit – Step Two

- Although not necessary, the Federal Circuit then considered step two.
- The Federal Circuit determined that the claims of the '929 Patent recite an improved process for preserving hepatocytes for later use, which is sufficient to be considered a patent-eligible concept.

Federal Circuit – Step Two

- Although the step of freezing and thawing hepatocytes was well-known, the Federal Circuit stated that the process of preserving hepatocytes by repeating the steps of freezing and thawing was far from routine and conventional.

Federal Circuit

- Therefore, the Federal Circuit held that the claims of the '929 Patent are not directed to a patent-ineligible concept, so the district court's decision was vacated and remanded.

Comparison

District Court

- Step 1: The claims are directed to an ineligible law of nature.
- Step 2: The patented process lacks the requisite inventive concept since the inventors reapplied a well-understood freezing process.

Federal Circuit

- Step 1: The claims are directed to a new and useful lab technique for preserving hepatocytes.
- Step 2: The claims recite an improved process for preserving hepatocytes for later use.

– Repeating freezing and thawing was not routine

Claim 1 of the '929 Patent

- A method of producing a desired preparation of multi-cryopreserved hepatocytes, said hepatocytes, being capable of being frozen and thawed at least two times, and in which greater than 70% of the hepatocytes of said preparation are viable after the final thaw, said method comprising:
 - (A) subjecting hepatocytes that have been frozen and thawed to density gradient fractionation to separate viable hepatocytes from non-viable hepatocytes,
 - (B) recovering the separated viable hepatocytes, and
 - (C) cryopreserving the recovered viable hepatocytes to thereby form said desired preparation of hepatocytes without requiring a density gradient step after thawing the hepatocytes for the second time, wherein the hepatocytes are not plated between the first and second cryopreservations, and wherein greater than 70% of the hepatocytes of said preparation are viable after the final thaw.

Practice Tips

- If the inventor makes a discovery of what is arguably a law of nature or other patent-ineligible subject matter, the inventor is still in a position to claim applications of that knowledge.

Practice Tips

- Thus, inventors should consider how a natural discovery can be applied in new and improved ways in order to arrive at a patent-eligible invention.

Practice Tips

- Similarly, patent practitioners drafting the patent specification must consider how a natural discovery can be applied in new and improved ways in order to draft patent-eligible claims.

Practice Tips

- Importantly, when a practitioner is concerned about a particular application being patent-ineligible, he or she must convey those concerns clearly to the inventor.

Questions?
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